**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| **UNIFORMED FIRE OFFICERS ASSOCIATION FAMILY PROTECTION PLAN LOCAL 854 and UNIFORMED FIRE OFFICERS ASSOCIATION FOR RETIRED FIRE OFFICERS FAMILY PROTECTION PLAN,** | **CIVIL ACTION NUMBERS:** **3:21-cv-12061-ZNQ-RLS** **3:21-cv-12747-ZNQ-RLS** **3:21-cv-10309-ZNQ-RLS** **ORAL ARGUMENT** |

**Plaintiffs,**

**v.**

**AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN CORPORATION PLC, BASF AMERICAS CORPORATION, BASF CORPORATION, BASF PHARMA (CALLANISH) LTD., BASF USA HOLDING LLC, CHEMPORT, INC., NISSHIN PHARMA, INC., NOVASEP LLC, NOVASEP, INC., GROUPE NOVASEP SAS, AND FINORGA SAS,**

**Defendants.**

Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608
September 27, 2022
Commencing at 11:00 a.m.

**B E F O R E:** **THE HONORABLE ZAHID N. QURAISHI, UNITED STATES DISTRICT JUDGE**

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(PROCEEDINGS held in open court before The Honorable ZAHID N. QURAISHI, United States District Judge, on September 27, 2022, at 11:00 a.m.)

THE DEPUTY COURT CLERK: All rise.

THE COURT: You may be seated. Thank you.

Today we are on the record for oral argument on a motion to dismiss -- actually, it's three matters; so let me just put those on the record and then I'll have appearances from counsel. But we've got *DRL v. Amarin*; that's docket number 21-10309. We've got *IPP v. Amarin*; that's docket number 21-12061. And a third related case, docket number 21-12747, which is the *Direct Purchaser, Plaintiffs v. Amarin*.

Let me get appearances from counsel, beginning with the plaintiffs. Why don't you go in order.

I'll start with DRL, then IPP, then DPP, and then I will hear from Amarin.

MR. PAK: Good morning, Your Honor.

This is Chul Pak from the Wilson Sonsini firm appearing on behalf of Dr. Reddy's Labs.

MR. RODRIGUEZ: Your Honor, also for Dr. Reddy's, Frank Rodriguez, from the firm of Windels Marx, and we have with us from the Washington D.C. office --

THE COURT: Get closer to the microphone. I'm having difficulty hearing, which means I think my court reporter is going to have difficulty.

MR. RODRIGUEZ: Also from the Washington D.C. office of Wilson Sonsini Goodrich & Rosati we have Seth Silber and Christina Clemens.

THE COURT: Welcome all. Good morning.

MR. CECCHI: Good morning, Your Honor.

James Cecchi, Carella Byrne, on behalf of the Indirect Purchasers. I'll let my colleague, Tom Sobol, introduce himself.

MR. SOBOL: Good morning, Your Honor. Tom Sobol, Hagens Berman Sobol Shapiro, LLP, for the Indirect Purchasers. With me is my partner Lauren Barnes.

THE COURT: Good morning to all of you as well.

MR. GATELY: Good morning, Your Honor.

Matthew Gately, Cohn Lifland Pearlman Herrmann & Knopf, LLP. We are liaison counsel for the DPPs. Also with me is Linda P. Nussbaum and Michael L. Roberts, who are co- and term lead counsel.

THE COURT: Good morning, Mr. Gately, and all of you. Let me hear from Amarin as well.

MR. BATON: Good morning, Your Honor.

Bill Baton of the Saul Ewing law firm, New Jersey counsel for the Amarin defendants. With me today is Tim Hester and Ashley Bass from Covington & Burling.

THE COURT: Good morning to all of you as well. I know you guys have discussed a bit about timing and

how you wanted to go with argument, but I mean, it's your motion, Amarin. Are you guys going to address your motion first?

Before you do, I just want to clarify -- well, two things I want to clarify on the record. The first is the briefs, including the motion, the opposition reply, were all sealed, but I just want to confirm on the record that this hearing, this oral argument is not sealed and that that is amenable to all the parties.

Is that correct from the plaintiffs?

MR. PAK: Your Honor, that is correct, with the exception that permission to review the transcript, to make sure there's nothing in there that is highly confidential and we might have to ask for a redaction. Otherwise, we can proceed in open court, Your Honor.

THE COURT: I intend to direct that the transcript be sealed until the parties have had an opportunity to review it.

I presume that's without objection from Amarin, Mr. Baton.

MR. BATON: No objection.

THE COURT: I have one other issue I just want to clarify. I have a separate timetable, timeline of key facts, and it talks about -- well, I have this PowerPoint piece of paper here. I have no idea who provided it. So can we put on the record where this originated? I want to make sure that

all the attorneys actually have this and this isn't something that I'm holding onto.

Is this from DRL?

MR. PAK: It is collectively from all the plaintiffs, DRL plus the class plaintiffs. We worked on it together. We submitted to Your Honor Friday evening.

THE COURT: This is from all the plaintiffs collectively. That's fine. I presume Amarin has a copy of this?

MR. BATON: They provided us a copy yesterday.

THE COURT: All right. It's only two pages, correct? I have a front and back, but that's the entirety of the document?

MR. PAK: It is, Your Honor. Frankly, I doubt that we'll reference it, but just because dates are confusing, we provided it simply for that purpose.

THE COURT: That's fine. Well, then is there anything further from the plaintiffs regarding housekeeping before I hear from Amarin, or --

MR. CECCHI: No, Your Honor.

THE COURT: Mr. Baton, who is speaking on behalf of the team over there?

MR. BATON: Ms. Bass will be.

THE COURT: Ms. Bass, it's your opportunity. You've got the microphone.

MS. BASS: Good morning, Your Honor.

Ashley Bass on behalf of the Amarin defendants. One small housekeeping matter. I think I'll go first and then the plaintiffs will have an opportunity then to go. So if I could reserve maybe 15 to 20 minutes for rebuttal time at the end, that would be greatly appreciated.

THE COURT: That's fine by me.

MS. BASS: Thank you.

Your Honor, I would like to first focus on the DRL complaint. The IPP and DPP complaints are simply derivatives of DRL's complaint, meaning that if the DRL complaint fails to state a claim, the IPP and DPP complaints should be dismissed as well.

DRL claims that Amarin has locked up the supply for API for Vascepa® to prevent generic competition. DRL's own allegations demonstrate that this is simply not the case. Those allegations show that generic competitors lined up supply, including from suppliers that were not supplying Amarin, and that generic competitors have launched and are currently selling generic Vascepa® in the marketplace.

THE COURT: Let me ask you this only because -- and I'm happy to hear everything you want to put on the record, but to educate me, is it Amarin's position that there's no circumstance whatsoever where you can have a violation of the antitrust laws when you have exclusive agreements with all

suppliers?

Let me give you an example. Say Amarin locked with exclusive agreements every supplier of the API knowing full well they don't even need that volume of the ingredient and the sole purpose is to prevent competition against your drug. Under that circumstance -- and I'm not saying it's true -- but is it your position that even then you can't have a violation of the antitrust laws? Or are you saying, no, Judge, there is circumstances where you could have a violation, but it didn't happen here?

MS. BASS: It's the latter, Judge.

THE COURT: Okay.

MS. BASS: And that is based on the fact that DRL itself has alleged in its own complaint. So here DRL has failed to allege any anticompetitive effects or antitrust injury because its own allegations show that Amarin did not prevent generic competition in the generic competitor's lined up API supply.

As a result, there's no need for this case to proceed into discovery on Amarin's supply arrangements or the reasons --

THE COURT: Now, I'm going to go back to what I asked.

Isn't DRL alleging that you did -- maybe not exactly my hypothetical, but aren't they alleging you did something like

that? That you guys locked in exclusively suppliers of this particular active ingredient for the purpose of preventing competition so that they could never launch their generic drug properly because you have locked in these suppliers? And on top of that, you didn't even need the volume.

Again, I'm not saying that that's accurate, but isn't that what DRL's alleging?

MS. BASS: Well, two things, Your Honor.

Their own facts allege that they actually received FDA approval in August of 2020 and that they had two suppliers lined up by September of 2020. And, indeed, one of those suppliers that they alleged that they lined up potentially could have been KD Pharma, but they didn't line up KD Pharma because they actually turned down the price offer from KD Pharma.

So this is a situation where even though DRL makes allegations that it claims that we've locked up supply, their own allegations show otherwise with respect to DRL's own ability to line up supply. And, indeed, Hikma launched as soon as the patent case was resolved and was immediately supplying API --

THE COURT: Well, I mean, Hikma is not a party to the litigation, correct?

MS. BASS: Correct.

THE COURT: And I don't know all the details on

Hikma, but at least the plaintiffs -- or at least one of the plaintiffs alleges that Hikma launched, but they didn't launch properly, meaning they didn't even have sufficient supply of the API when they launched; so they launched with a lower volume of it. And even that necessarily wasn't a proper launch.

But they're not a party. How do I know what happened with Hikma? How do I compare that?

MS. BASS: Well, Your Honor, Hikma launched -- and I can go through the timeline of when they launched to show that there was no delay. And the point here then is that under the legal standard the plaintiffs need to be able to show substantial foreclosure and that there was a significant impairment on competition in the marketplace.

And if Hikma launched and they got access to API, and it was not from an Amarin supplier, then it makes the allegation that there's been some sort of lockup by Amarin completely implausible here.

Because with your indulgence, Your Honor, if I could walk through just seven key dates that show that there was no delay in terms of generic competition gaining access to the market here.

THE COURT: Go ahead. That may be helpful. I'm happy to hear from you.

MS. BASS: Here's the key dates. On March 30th,

2020, the trial court rules that Amarin's patents were invalid.

On May 21st, 2020, Hikma received final FDA approval for its product. So Hikma did not have FDA approval until May of 2020.

DRL received final FDA approval on August 7th of 2020. Again, DRL did not have the ability to sell its product in the marketplace until August of 2020.

On September 3rd of 2020, the federal circuit affirmed the district court opinion. By September of 2020, DRL's own allegations indicate that they have lined up two suppliers. So only one month after they received FDA approval, they had two suppliers lined up. Those suppliers included BASF.

According to their own allegations, BASF was a supplier with sufficient capacity to support a timely and full commercial launch and it was a world leader in this space. And they also engaged another supplier that they reference but do not name in their complaint that they lined up by September of 2020.

On November 4th, 2020, the federal circuit denies rehearing in the patent case. November 4th. November 5th, Hikma launches the next day.

Clearly Hikma had supply --

THE COURT: Who supplied Hikma?

MS. BASS: Apparently it was from a supplier not

related to Amarin, because DRL doesn't make any sort of an allegation that Amarin did anything to impact the supply that Hikma lined up and launched with the day after rehearing was denied in the federal circuit appeal.

So what do these facts tell us? It tells us that DRL could not have launched before August of 2020, and they had two suppliers lined up by September.

DRL itself alleges that one of those suppliers had sufficient capacity to support a timely commercial launch, and DRL doesn't even allege that the other supplier that they lined up was working with Amarin.

DRL acknowledges that Hikma lined up supply and launched the day after the resolution of the patent case at the federal circuit level. DRL even admits in their complaint that they did not start reaching out to suppliers until the April to May 2020 time frame; yet they had suppliers lined up by September of 2020.

So what conclusions do we draw from these facts? The conclusions that we draw is that there has been no foreclosure here. Hikma launched the day after the federal circuit denied rehearing, and DRL itself quickly lined up two suppliers to support its launch.

These pleaded facts cannot meet the legal standard to show that there was any sort exclusive dealing arrangement here that causes concern under the antitrust laws.

THE COURT: Ms. Bass, let me ask you this. I actually have one specific question and one that's much more general.

My specific question is, on the four suppliers that you had exclusive agreements with, is it your position, or do you disagree that those four suppliers were the primary suppliers of the active pharmaceutical ingredient for the generic drug, or are they just the same as any of these suppliers that are not really part of this discussion?

MS. BASS: I have two answers to that.

The first, Your Honor, is that for purposes of this Rule 12 motion, we have accepted DRL's allegation that we have exclusive supply arrangements with our suppliers. But for what it's worth, that clearly isn't the case because they lined up BASF, which is one of the suppliers that they claim has an exclusive agreement with us. That's number one.

Number two, obviously Hikma was able to line up supply, receive FDA approval, and launch with a supplier that is not an Amarin supplier. So there clearly are numerous other suppliers that are available in the marketplace, and indeed DRL makes extensive allegations regarding the fact that supply is available and it is easy to switch the production of official products over to this API.

So this is not a situation where there's only one provider of the API or, to Your Honor's point, as they might

allege, you know, four key providers. There's clearly many, and Hikma found one and launched.

So we're turning to the legal standard; if the Third Circuit has recognized --

THE COURT: Sorry. I have a more general question now. I'm going to get both my questions in.

Plaintiffs' counsel, don't worry, your time is coming.

Let me take a step back at this stage of the litigation. I want to tell you what I'm hearing and what I see in the briefs, and then you can explain to me why at this stage I should be considering granting your motion.

So intertwined with the antitrust claims and the tortious interference claims are a lot of factual disputes, right? For example, Amarin says the plaintiffs didn't do their due diligence, right? They didn't start early enough to secure suppliers, knowing that if they were going to win that fight and your patent was going to be invalid and they were going to be able to launch their generic drug at the time they were going to, they didn't do what they were supposed to do.

Plaintiffs say that's not true. Right? We did what we were supposed to do. Seven years prior to the launch we were securing suppliers and doing all these things, and but for Amarin's misconduct, we wouldn't have had the rug taken out from under us and prevented from getting our generic drug out timely and also in the way that we should have been able to

put it out because we ended up buying API. By the way, that's only one.

Also intertwined with these legal issues is an argument that the plaintiffs make about Amarin, that you didn't even need these suppliers, that your sole purpose for securing these suppliers of the API at the time that you did was primarily to prevent competition.

Your position is very different. It's no, we're global. This was a drug that was being marketed not just domestically, but internationally. And so the suppliers that we secured were necessary not only for the volume of product that we were putting out on the market, but we were looking to expand. So there again is another, I would argue, factual dispute between the parties.

And then let me just put out one more example. Well, no, I'll use those two examples, or those two and a half examples there.

So we're at the motion to dismiss stage, right? There's been no discovery done to really determine a few things. One is what really was behind Amarin's securing these suppliers. Was it to somehow prevent competition, or were you doing what you guys have argued in your papers, which is there's nothing that's illegal or impermissible about having exclusive agreements with suppliers to assist us in getting our products manufactured and marketed? That's one. That

there's no discovery being done.

Also, there's no discovery on the other issue that I raised. Not just, you know, on I guess the plaintiffs' due diligence, right? What did DRL do?

They argue that they spent a significant amount of time trying to secure these suppliers, and but for the actions of Amarin, they would have been good to go at the time of launch. And you guys say they didn't do their due diligence. Again, no discovery done and another factual dispute.

So my broad question for Amarin is this: How at the motion to dismiss stage am I authorized to grant that motion when these factual disputes are intertwined with both legal claims? And isn't this more ripe -- well, maybe more ripe for summary judgment, although I'm not so sure about that, because if you have material facts that are in dispute, by the end of this rainbow, nobody's granting summary judgment, since that would be a primary reason to deny it. But then I would say, if not at that stage, aren't these issues ripe after discovery and then battled in the well of a courtroom at trial?

MS. BASS: I understand your question, Your Honor. And we would submit that there are plausibility issues with certain of the facts that you just pointed to as being in dispute. But luckily you can set all of that aside because the issue here is that there is no anticompetitive effect. When Your Honor considers reaching a decision on a motion to

dismiss, the seven key dates that I pointed out at the beginning of the argument are the ones that drive the decision.

Those dates demonstrate that there was no anticompetitive effect here because there was no exclusion. And that meets with the legal standard. So that's something that we haven't yet discussed today, but it's worth us pausing on for a minute.

So in terms of exclusive dealing arrangements in the Third Circuit -- and there's nothing inherently unlawful in the Third Circuit's view of exclusive dealing arrangements. Indeed, the Third Circuit has recognized that exclusive dealing arrangements are frequently upheld and found to be completely lawful. This is because they are often highly efficient and create a lot of benefit for the parties in terms of price, stability, and outlets, and often pose --

THE COURT: I don't necessarily disagree with that law, but at the beginning of this argument we discussed that Amarin would concede, though, there are circumstances where you can have exclusive agreements with suppliers and you could violate the antitrust laws, right?

In other words, although there's nothing inherently improper about having exclusive agreements with suppliers, and that is something that's been held by the Third Circuit, in this circumstance and other circumstances there are scenarios

where these exclusive agreements are solely done to prevent competition and you can fold them into a different pool, right? You can then have conduct that's a violation of the antitrust laws.

So I just want to make sure that we're clear. I don't necessarily agree with Amarin's general position on the law of exclusive agreements, but this is a lot more specific. The plaintiffs aren't saying you violated the antitrust laws because you had exclusive agreements with suppliers of the API. They're saying you've done much more than that, and that the sole purpose in what you were doing was really to prevent competition, not to do what Amarin is claiming, which is, hey, we have a drug. We need supply for the active ingredient, and so we went to the suppliers, like any other business would do in order to get it.

So how are the plaintiffs wrong there? That they're alleging much more than just exclusive agreements for suppliers of the API?

MS. BASS: Under the Third Circuit law, the point that I was -- the next point that is very relevant is that because we all agree that there are certain circumstances where these agreements can be lawful, the Third Circuit then has described when they can be problematic, and that's really the focus of what we're looking at here today.

And these types of exclusive dealing arrangements can

potentially be problematic if there is substantial foreclosure that prevents meaningful competition in the marketplace. So the Third Circuit has been clear that the test is whether the agreement bars a substantial number of rivals, or severely restricts the market's standing.

So that's what we're looking for. We're looking for something substantial, something -- it has a very strong impact on the marketplace. And, indeed, in the *Jefferson Parish Hospital* case, which is a Supreme Court case, the concurring opinion there said it well: that what you're looking at is, are people frozen out? Has there been a freezing out of competitors?

And here the issue is that DRL and the other plaintiffs cannot show that there has been any substantial foreclosure or any anticompetitive effect from these agreements because Hikma launched the day after the federal circuit resolved the patent case and DRL itself lined up two suppliers by one month after they received FDA approval.

THE COURT: Are you saying they can't show it or they didn't plead it? Because those are very different statements to make. You keep saying "can't show" and I'm saying we're at the motion to dismiss stage; so how can they show me anything when they've had no discovery? But are you saying they didn't properly plead that?

MS. BASS: Your Honor, it's a very good point,

because actually the point is that these are things that are pled in DRL's own complaint. They have pled themselves out of the case here because they have pled that Hikma did launch once the federal circuit case was resolved, and they have alleged and they go through in detail that they lined up suppliers by September of 2020.

And, indeed, they even allege that they could have lined up KD Pharma, but they rejected a price from KD Pharma. These are all allegations in their own complaint.

THE COURT: So is it Amarin's position that if a generic manufacturer can launch -- and we'll use that term pretty broadly. The launch is equal no matter what type of launch it is, right?

So if the generic drug launches, but they only have a limited supply of API and so they're not really marketing the drug in the manner in which they intended to launch it because they don't have enough supply, are you saying in Amarin's position, hey, it's a launch? And for them to have had a better legal position, at least at this stage of the litigation, they shouldn't have done anything?

Because I guess my point is, should the plaintiffs be penalized for trying to launch their generic drug, not in the volume and manner they wanted to, but now they have a worse legal position for it? As opposed to saying, well, because we have a limited API supply, because we don't have a supply

because Amarin cut us off, we might as well not launch at all because that will give us a better legal posture in federal court.

I don't know if that's the right message to send. Just because a plaintiff has launched the generic drug doesn't mean that's equivalent to launching it in the manner that they believed they should've been entitled to but for the conduct of Amarin.

So do you see a difference there? Or are you saying a launch is a launch? They shouldn't have launched the drug and then claim that they were injured here.

MS. BASS: I think here based off of their own allegations, the launch is important. We're not saying a launch is a launch. But here, Hikma launched. And they made just a very passing statement that it was in some sort of a limited quantity, but there's two very key pieces of information with respect to that absolutely-not-supported allegation that is made in the complaint.

Number one, Hikma did find supply and did launch, clearly. Number two, this is a drug --

THE COURT: We don't know -- but then going back to that. If you agree with me that a launch is not a launch, and there's a difference between it, what information do I have about Hikma's launch? How can I even compare it, because they're not a party to the case. There's no information other

than the plaintiffs are saying, look, Hikma launched, but not in the way they intended. They had a launch with much lower volume of API because they were hindered, similarly to DRL. But I don't have that before me.

So how can I even use Hikma as a factor in anything when I don't know what it means when they've launched the generic?

MS. BASS: I think, Your Honor, that it shows that the allegations are not plausible. It's DRL's responsibility to set forth plausible allegations that there has been substantial foreclosure.

If Hikma has launched and they want to try to make an argument that it was limited in some way, it was their burden to support that. Now, the only piece of information that they tried to point to to try to argue that it was limited is the concept that Hikma received 15 percent of sales six months after launch.

First off, 15 percent is a good bit. Second off, the very important part about this drug is that Hikma and DRL are only approved for the first indication of the drug. They do not have FDA approval for the second indication of the drug. That's what DRL tries to plead, is some sort of a limited launch is completely plausible as to what one would expect for a generic competition, a competitor like Hikma, to launch when they only have approval for the first and smallest indication

associated with the drug.

Again, these are all facts that are alleged in the complaint, that both Hikma and DRL carved out the second approval from their label and only launched with the first indication.

So, Your Honor, I would submit to you that Hikma is very relevant here, because if DRL wants to try to claim that there was some sort of a limited launch by Hikma, then they have to plead plausible facts to support that. And not only that there was some sort of a limited launch in DRL's eyes, but that Amarin did something to impact that launch.

Clearly Hikma has lined up a supplier that is not an Amarin supplier. So there's no plausible allegations that Amarin did anything in order to impact the ability of Hikma to --

THE COURT: When you say they secured a supplier, I don't know if that's the right word, but I'll just use the word "secured." Hikma secured a supplier. When you say that, it sounds like if they found a supplier, they're good to go. You had four suppliers.

So this idea that one supplier necessarily makes it sufficient that they're going to get the volume of ingredients to manufacture drugs, I'm not so sure that that's accurate. Because why did you need more than one supplier? Why did Amarin need more than one supplier if securing a supplier

should mean that you're fine?

MS. BASS: Certainly, I think that Amarin has a very long history in this marketplace and a very long history investing and helping its suppliers to grow. But the bottom line is that Hikma located supply and Hikma launched. And we have no plausible, well pled allegations here that that launch was limited in any way, or that it was limited by any sort of conduct by Amarin.

I think that's the key, that allegations are ones that DRL needs to make and DRL has not done so.

So, Your Honor, this is one of the things that I think is also important to pause on is the fact that the facts here are very different than the API supply cases that the plaintiffs point the Court to. In each of those cases there was some sort of an absolute exclusion of generic competitors from the marketplace for a substantial period of time.

That's not the facts we have here. We have launches and we have people lining up supply immediately upon resolution of the patent case.

THE COURT: Let me ask you this. If DRL, because they couldn't secure enough supply for the API and didn't launch, and then they filed the lawsuit, what would you have said then?

MS. BASS: Well, if DRL pled in their complaint that the reason they couldn't --

THE COURT: I'm sure they would have pled if they didn't launch. The reason we didn't launch is because we didn't have enough supply of API because of all the allegations we have in this complaint.

So I guess what I'm saying is the only difference in the complaint is, instead of launching, what DRL would say, insufficiently, but they just said forget it. We won't even bother launching at all. We're going to file this suit, because why bother launching with such limited supply? We might as well just say no launch and go forward. Would you have a different position than you have now because they are alleging that they were not able to launch?

MS. BASS: No, Your Honor, because what DRL alleges is that they went to KD Pharma in April, after the patent decision occurred. They tried to line up KD Pharma as a supplier. KD Pharma offered them a price and DRL rejected it. If DRL had accepted that price, they could have launched immediately. They have no allegations that there were any sort of regulatory issues with KD Pharma.

So, Your Honor, if there had been no launch by DRL, our position would be the same based on the facts pled in the complaint.

THE COURT: Understood. All right.

MS. BASS: So, again, the cases that the plaintiffs have pointed Your Honor to: *Geneva*, *Vyera*, *Fera*, and

*Fresenius*, are all cases where there was complete exclusion of a competitor from the marketplace for a significant period of time.

Indeed, in two of those cases the ANDAs were canceled and no generics ever received FDA approval. So the cases that DRL has pointed the Court to are ones where there was actual exclusion of competitors, complete exclusion for a significant period of time. That is not the facts that we have here.

So DRL offers two key rejoinders to that -- the fact that there has actually been entry into this marketplace and API that's available to --

THE COURT: Is it Amarin's position that it has to be total exclusion? If there's limited exclusion, meaning DRL is able to launch -- and again, I understand you're not agreeing with the allegation -- but I'm just saying if it's limited exclusion, we were able to launch, but we were limited because of these violations, is that somehow different than them saying we were fully excluded?

MS. BASS: Well, there's no allegation that they would have been launched -- limited in a launch with KD Pharma if they had accepted the price. So first off, there's no allegation --

THE COURT: Isn't there an allegation the reason they didn't accept the price was because it was unreasonable?

MS. BASS: With no well-pled facts to support that.

And it's convenient that KD Pharma offered them --

THE COURT: Well, I'm going to have DRL have an opportunity to speak on it, but I'm putting it out there. I didn't memorize the pleading. That part, you're on your own. I presume DRL is going to educate me what they're pleading some of those allegations are.

But I recall that there's at least some allegation from DRL that the reason why they couldn't accept that price is because it was something ridiculous.

Now, I don't remember all the allegations of every paragraph of the complaint, but isn't there something that alludes to that from DRL?

MS. BASS: There is an allusion, but again there is no well-pled facts to support what price was offered and why it was turned down. And if a price was offered by KD Pharma, and DRL turned it down, that's the reason they're not in the market today.

So, again, they pled that fact in their own complaint. They pled the fact that KD Pharma offered them a price and they rejected it, and then they went to look for other suppliers at that point in time.

THE COURT: Let me ask you this -- I know we are going to have a lot more questions; so accepting it as true, right, so say KD Pharma went to DRL and gave them this ridiculous price. Basically, it was an offer, but not really

anything. It was just to confirm that they were not going to make an arrangement. Would that change your mind about whether they received an offer from KD Pharma and they should have gone forward with the supplier?

I mean, believing that allegation to be true, that they were already supplying Amarin, is Pharma one of the four suppliers that's supplying Amarin?

MS. BASS: Yes.

THE COURT: Right. So they're one of the four suppliers. DRL comes to them and they say fine. You want to work with us and they give some outrageous price that no company would ever accept. In fact, it's almost insulting, other than it's so obvious that they're just doing that to confirm there's no relationship moving forward.

Under that circumstance, would you say, well, then that's not really an offer that they could have accepted? That makes no sense, in any business sense, and any reasonable company wouldn't have done that.

Would that change your analysis?

MS. BASS: I think, first off, there's no allegations along those lines. So even if that were the case, even if Your Honor were to find that the KD Pharma offer was completely unreasonable --

THE COURT: I thought they did make that allegation. Again, I'm going to ask them to correct me if I'm wrong, but

my recollection of the pleading is there is an allegation like that.

MS. BASS: They said that it was not economically rational for them to take the price. So, Your Honor, I mean, again, this isn't a price dispute between KD Pharma and DRL as to why DRL wouldn't accept the price and launch with their own supplier.

And the thing to Your Honor is, even setting aside the KD Pharma issue, DRL admits that by September 2020, they have lined up another unnamed supplier and they provide no information as to why they couldn't have launched with adequate capacities with that supplier, other than to say, well, there were regulatory issues that they needed to attend to. But they don't indicate what the timeline was for that unnamed supplier.

And indeed with BASF, they had also lined BASF up by September 2020. And they don't provide any information about why they didn't start the regulatory process sooner with BASF.

Bottom line is that Hikma launched. And Hikma launched with only approval for the first indication, which is assumed to be a very small portion of this marketplace. Indeed, the DPPs cite a press article in their complaint where the estimation is that the first indication is only for seven percent of the marketplace. Seven percent. And Hikma got 15 percent in the first six months.

So the concept that there's some sort of a limited launch here -- the word "limited" is in the complaint, but it is not supported and it is belied by the other factual allegations that are in this very same complaint.

So, Your Honor, additionally, if Your Honor wants to credit that there's some sort of a transitory delay here, some -- Hikma launched the day after the federal circuit decision, and maybe if you want to credit that it was limited in some way, or you want to credit that DRL claims their launch was limited. Here you have Hikma launching. You have DRL launching ten months later.

So as our briefs explain, that very limited amount of time is viewed as transitory under the antitrust laws and not actionable. It is not anticompetitive effect for there to be some limited, non-substantial temporary impact on competition in the marketplace. And the purported delays alleged by DRL fall squarely within the cases that have found that there was no anticompetitive effect under the antitrust laws.

So we discuss these cases in our briefs. For example, in *Adaptive Power* there was a four to ten month delay in production of a competing product.

In *Jane Fine Chemicals* there was a five to nine month delay where there was a complete absence of generic competition.

In *Pro Caps* there was a seven month period where the

restraint was in place.

And in *Williamsburg Wax* it was a whole year.

And these courts found that there was no anticompetitive effect in that situation, because what we're looking for under the antitrust laws is something that has a substantial, a market-wide impact, not an impact on the single competitor: an impact on competition.

THE COURT: Isn't the allegation though, Ms. Bass, that it's not just delay, that they continue to be harmed because they're limited in being able to compete with Amarin because they can't get sufficient supply of the API? Again, I'll have DRL correct me if I'm wrong, but isn't that generally part of their allegation? That it's not just a delay in any kind of launch. It's the current state of what they're able to do because they're not able to obtain sufficient supply of the ingredient.

MS. BASS: Well, Your Honor, they were able to line up two suppliers by the point after -- one month after FDA approval. They were able to launch ten months later. And, again, we keep coming back to Hikma, but they have no answer to the fact that Hikma launched the next day after the federal circuit resolved the issue.

So, again, what we're looking for here is harm to competition across the marketplace, not just harm that -- purported harm to DRL. So I think that that's the key here,

if they hadn't made these allegations in their complaint, maybe we'd be assessing a different case.

But their own allegations in their complaint show that there is no anticompetitive effect here. And that is what is really critical. That's why we don't need to move into discovery to address the issues that we talked about at the top of the argument, because with no anticompetitive effect there can be no antitrust cause of action.

And their own facts, as pled, demonstrate that there was no substantial foreclosure here and there was no anticompetitive effect.

So what is DRL's final rejoinder? The final rejoinder is one we talked about a good bit today, that the Court shouldn't decide this issue on a motion to dismiss.

Certainly the Third Circuit has no issue affirming district court judges that find --

THE COURT: We're always right. They're not going to reverse me.

MS. BASS: The complaint should be dismissed when they cannot make out a claim under the antitrust laws. There's no issue there.

And certainly that was the case in the recent *Uber* case where the Third Circuit affirmed the district court judge on the finding of no anticompetitive conduct and no antitrust injury.

And this is even more of the case when the legal assertions that a party is making are completely belied by the factual allegations in the complaint. That is what the *Schuykill* case in the Third Circuit tells us.

And certainly *Twombly* itself was a Supreme Court affirmance of a dismissal of an antitrust claim that did not cross the line from conceivable to plausible. And *Trinko* itself was also an affirmance of the dismissal of an antitrust claim that was not anything problematic under the antitrust laws.

So the bottom line here is that this is a case where DRL's own allegations show that it cannot plead antitrust injury or substantial foreclosure based on its own objective pleaded facts.

Hikma lined up a supplier that was not an Amarin supplier, and DRL lined up two. Given the facts as pleaded, DRL cannot demonstrate that Amarin locked up supply through its supply arrangements and cannot meet its burden to demonstrate that Amarin's agreements had any sort of concern under the law of exclusive dealing.

Your Honor, I wanted to turn to tortious interference and the IPPs, but I want to make sure we've covered all of your questions on the core --

THE COURT: No, I appreciate it. I know I had some questions, but I do appreciate you responding to them and then

going back to your argument. So thank you. Do you want to switch to the other claim?

MS. BASS: So that covers the antitrust claim for DRL. As I mentioned at the beginning, because that claim falls, the IPP and DPP complaints fall as well.

So let's discuss a few other kinds of items that are unique to some of the different complaints and make sure that we cover those as well.

The first is DRL's assertion that there was tortious interference here. As we described in our papers, there are multiple flaws with that theory. The first being that DRL has no plausible allegations that Amarin understood that there was any sort of a contractual relationship or arrangement between KD Pharma and DRL. That's the most basic fact that needs to be pled in order to plead out a tortious interference claim, and it is not available here.

In addition, the plausibility of the allegation that a contract even existed between KD Pharma and DRL is also questionable on the facts as pleaded. In the complaint, DRL refers to whatever this contractual arrangement is as a term sheet. Clearly it didn't set the price, because KD Pharma offered a price to DRL, but DRL rejected. And clearly it didn't set forth the capacity or amount that was to be purchased, because DRL pleads in its own complaint that the term sheet just said something about sufficient capacities

would be provided.

So there's a question here as to whether or not there's even an actual contract between DRL and KD Pharma that could have been tortiously interfered with.

But nonetheless, we're turning to the point I just made. The real issue here, in addition to no knowledge and in addition to whether there's a contract, is a causation point. Any lack of a relationship that moved forward between KD Pharma and DRL is because DRL rejected the price offer from KD Pharma, not because Amarin tortiously interfered with some sort of a relationship between the two parties.

So, again, based off of their own facts pleaded in DRL's complaint, they cannot make out a tortious interference claim here with contract.

And their other claim for some sort of interference with prospective economic benefit is even less well pled. I don't know who these agreements were supposed to be with. I don't know what we were supposed to have done to interfere with them. There's absolutely no facts to support that there was any sort of economic benefit that was tortiously interfered with that should be actionable before the Court.

So we wanted to just note that the tortious interference claim is completely improperly pled and should not survive this motion to dismiss, again, based off of DRL's own facts as pleaded.

So turning to the IPP complaint. I'm sure Your Honor enjoyed the very lengthy briefing on the IPP state law claims. I will not belabor the briefing, but there's a few key points that we would like to note for the Court because the state law claims obviously required a lot of paper and so we wanted to touch on them for a minute.

I mean, the bottom line is that if the federal antitrust claims fall, the IPPs have provided Your Honor with no basis to think that any of their state law claims should continue. So they have state law claims under antitrust statutes, consumer protection statutes, and common law unjust enrichment. Here if the federal antitrust claims fall, certainly all of the those claims should fall as well.

In addition, as our brief has noted, there are also standing issues with respect to the named plaintiffs here. The plaintiffs are only entities in New York, in New Jersey, yet they're trying to assert a myriad of claims across dozens of states that they don't plead they have any connection to. So they have a major standing problem.

And certainly courts within the Third Circuit have noted that there's an Article III standing issue when a plaintiff attempts to assert a claim in a state where it has no connection to that claim.

Our briefing also notes that there are a number of state specific type arguments with respect to the indirect

purchaser state law claims. These have to do with things like no allegation of nexus to the state, states not permitting indirect purchaser suits, limiting rights, cause of action to consumers, and states that require deceptive conduct, where none is pled here.

I'm happy to answer any questions on the IPPs state law claims, but I think we adequately covered them in our briefing.

THE COURT: I agree and I don't have any additional questions.

MS. BASS: Perfect.

One small note of something that was in our complaint that is worth noting here: you know, the IPPs for the New Jersey plaintiffs are only asserting an unjust enrichment law -- claim under state law. So they have their federal injunctive relief claim, but their state law claim is only an unjust enrichment claim. And our briefs point out that once they -- you know, they cannot bring a claim under New Jersey law because New Jersey does not permit indirect purchasers to bring suit. So they have no statutory based claims.

And the cases are very clear and consistent that a plaintiff cannot use unjust enrichment as an end-run against that New Jersey statutory pronouncement that indirect purchasers cannot sue.

So this is described in our brief, Your Honor, but we

wanted to pause on the notion that the New Jersey plaintiffs here have a serious issue with respect to the causes of action that they are asserting.

In conclusion, here Amarin submits to the Court that you should dismiss this case with prejudice. This is a case where DRL has pleaded itself out of its claim.

THE COURT: Well, wait. With prejudice. I mean, most of the arguments that you are making is that they didn't have enough allegations; they allege this, but they're not specific enough.

I mean, how is that with prejudice? Why wouldn't I allow -- even if I agree with you, and I'm not saying I'm there, but even if I did, why wouldn't I at least give these plaintiffs an opportunity to cure their pleading?

MS. BASS: Well, Your Honor, they can't take back the allegations they have already pled. I mean, those --

THE COURT: No, but they can be more specific, right? So, for example, where you're arguing, well, Judge, they pled that the KD Pharma was unreasonable, but they don't give us enough. They don't say anything more about that, right? That's part of the argument that Amarin has. There's been more than one occasion where you've taken that position.

So wouldn't I, at minimum, even if I agreed with Amarin, allow them the opportunity to provide more specific allegations in the areas that you guys have argued are

deficient?

MS. BASS: You can't change the fact that they have pled that they lined up two suppliers by September of 2020 and that they had the opportunity to do -- with KD Pharma and there wouldn't have been any regulatory issues but for this financial issue.

So, Your Honor, we would submit that the facts as pleaded mean that they have pled themselves out of the case here, and any sort of amendment that happens will not change those core facts and those core dates that we discussed at the beginning, including the fact that Hikma launched the day after the resolution of the federal case.

So because DRL cannot make out such a claim, also the IPPs and the DPPs cannot. As we discussed at the beginning of the argument, their claims are simply a copycat and derivative of DRL's complaint. So if DRL's complaint falls, the IPPs and the DPPs fall as well.

Thank you, Your Honor.

THE COURT: Thank you. I appreciate that.

Mr. Pak, are you coming up?

I mean, Amarin wants your case gone forever. They don't even want to give you a shot at trying to fix it. So you're going to try to convince me it doesn't need fixing.

MR. PAK: I heard that. With prejudice, no less.

THE COURT: I will allow you to present your

argument, but expect I may have some questions.

MR. PAK: Yes, Your Honor. Thank you very much. Chul Pak for Dr. Reddy's Laboratories.

Let me just start with what is probably fresh in your mind, based upon some of the things that were discussed by Amarin's counsel.

Let's first talk about this concept of launch. You actually were very astute to note there are different degrees of launch. There is launch of where you sell one pill. There's a launch where you sell -- ultimately reach the forecast you have of millions of pills, bottles, et cetera. That's what we're talking about. It isn't just launch. It's effective launch, plus it's delayed launch, and that's what happened here.

Sure, September 2020 we got -- August 2020 we got ANDA approval and immediately we could have started production, ramping up, things like that. But we found out our principal supplier was not available to us. And it wasn't just on price, by the way. They first told us -- and it's alleged in the complaint, paragraph 67.

THE COURT: We're talking about KD Pharma?

MR. PAK: Yes, Your Honor.

THE COURT: What's the name of the company?

MR. PAK: KD Pharma.

THE COURT: Let's talk about KD Pharma for a bit,

only because that's freshest in my mind because they were addressing tortious interference.

First, in the complaint, where do you allege -- again, I don't have your pleading memorized. Where do you allege that Amarin even knew that you had an arrangement with KD Pharma?

MR. PAK: It seems to me, Your Honor, there are a couple of places where -- as to the tortious interference. During the course of the patent litigation that Amarin commenced to keep us out of the market -- we defeated that finally and were able to launch -- there are references to KD Pharma there.

Second, it's quite likely, Your Honor -- I can't prove this -- but when Amarin walks into KD Pharma's door in 2019, whenever they did that, they say, hey, we want 400 metric tons, even though the U.S. market only demands 450 metric tons, it seemed more likely than not, Your Honor -- we weren't there -- that KD Pharma would have said --

THE COURT: Let me ask you this.

MR. PAK: We had to supply --

THE COURT: Where is it pled? We're at the motion to dismiss stage. So have you pled that Amarin was aware of the arrangement that you had with KD Pharma? I'm saying arrangement, whatever word you want to use. Contract, agreement, relationship, whatever it may be, and knowing that

relationship, they took steps to interfere with it. If you have that, it's helpful not only for me but for my law clerk to have that on the record during oral argument. Where in the pleading are you arguing you've sufficiently pled those issues? I know it's in your briefs, but where is it there?

MR. PAK: If you're asking me literally off the top of my head right now which paragraphs are they, I will either ask my colleagues to hopefully find it during the course of our discussion today, or if Your Honor would permit subsequent.

THE COURT: Have you identified those specific paragraphs in your written submissions to the Court?

MR. PAK: We did, Your Honor.

THE COURT: Well then I'll rely upon that, but what you're arguing is that we did plead that they were aware of the relationship between DRL and KD Pharma. So this isn't something that wasn't pled in the complaint.

MR. PAK: We think it is pled in the complaint, and we are arguing and saying whether it's constructive notice or actual notice, they knew that we had this relationship with KD Pharma.

THE COURT: All right.

MR. PAK: That was the issue just of launch, whether or not launch happened or could have happened, et cetera. It seems to me the entire case for them seems to rely on the fact

that Hikma and DRL ultimately did find some suppliers.

First of all, with respect to Hikma, we have no idea how they did it or what they did, and they, too, could have suffered from the same problem.

THE COURT: Let's talk about your suppliers. Let me ask you this: Before we even talk about suppliers, would you concede -- and Ms. Bass identified this issue before she sat down -- that there is case law out there that says delay alone is not sufficient to establish the claims that you are making? Would you concede that point, or you do not agree with that?

MR. PAK: I do not agree with that.

THE COURT: You believe that delay in and of itself is sufficient, but in this case, Judge, you don't have to worry about that because we have more. We have delay plus we had an insufficient launch plus we currently are in the state in which we are being prevented from competing because of their conduct. Is that where you are?

MR. PAK: That is correct, Your Honor. It's alleged in our compliant and their case law as well. Remember, if I may just explain a little bit, these are generic drugs. What happens in the industry when a generic drug enters? It depends on whether you're the first, second, third, fourth, et cetera. With each new generic entrant, typically prices come down substantially. And the branded company, Amarin, typically loses sales because patients switch out, doctors

prescribe or the patients switch out their generic; they're the equivalent. So with more generic entry, prices come down. It's not just about Hikma or Amarin -- I'm sorry, DRL, one or the other. With more generic entry, prices come down. And with delayed entry, that means consumers don't get the benefit of those lower prices on day one. Instead they have to wait. So if we were ready in September of 2020 to launch, okay, consumers would have benefited right away from Hikma with lower prices. Instead we were only able to launch starting in June of 2021. That's a ten month period. During those ten months, Amarin, remember, Amarin is the monopolist here. We allege that. They don't dispute it. They control the market. They control all the API. They control the drug itself downstream. And in that situation, when you're a monopolist --

THE COURT: Well, they don't control all the API. You had two suppliers, correct?

MR. PAK: Your Honor, that would be a factual issue.

THE COURT: You had to launch with a supplier, correct?

MR. PAK: We allege, and it's in paragraph 114, Your Honor. We say that those five suppliers at that time, right, were the only available suppliers who could provide API. Sure. Later, new suppliers can come in in the sense of we can get FDA approval. The FDA can go visit the factory to see if

they can really make the API, and that's what happened.

THE COURT: I'll let you present, but I need you to answer what I need to know. So, first of all, you say five. Is it five or four suppliers that Amarin secured with exclusive agreements?

MR. PAK: Four originally, and then they took KD Pharma and it's five.

THE COURT: Are you saying at the time that you launched, those five, including KD Pharma, were the only suppliers of the API that could do it at that time?

MR. PAK: When we received approval and were hoping to launch in September, those were the only five that were FDA approved and ready with capacity. And then when KD Pharma was taken away from us, that is significant because when we applied to the FDA, saying we're going to sell a generic, we have to reference who our API supplier is going to be. We said that's going to be KD Pharma. We've been working with them since 2013. We sent the FDA in. The FDA approved KD Pharma to be a supplier.

So come 2020, now we think everything's ready. We're ready to go. We find out KD Pharma is not available to us. They tell us there's no --

THE COURT: Didn't KD Pharma leave DRL hanging, not Amarin?

MR. PAK: Well, that's because Amarin went in and

entered into an exclusive contract, saying, hey, we're going to buy up 400 metric tons of your API.

THE COURT: Now, was it exclusive? Because I thought the reason why you ultimately didn't go forward with KD Pharma is because they gave you an unreasonable price point that you said didn't make sense.

MR. SOBOL: Oh, no, Your Honor. That's what they said.

THE COURT: Okay.

MR. PAK: Our point is they told us they couldn't sell to us. They also didn't have capacity. And when we offered them more money, we offered them a higher price.

THE COURT: They still said no.

MR. PAK: They still said no, and they did come back to us. You pointed out, they came back with a price that basically would have made it uncompetitive --

THE COURT: So they ultimately did do that. That's what I'm trying to tack down, Mr. Pak, because you just said it was their point. My point is simply that they ultimately come back to you, but they gave you a price that you said was so unreasonable it was tantamount to not bothering to have any agreement with you at all.

MR. PAK: It's a three-point. But, yes, Your Honor. It was a three-point. Price, way too high, unprofitable for anybody to make it. Two, they said they had no capacity to

give us API. Three, they said we don't think we can give it to you because we've got an exclusive with Amarin and there are penalties associated with that.

THE COURT: So at the time that you ultimately get a supplier for the launch -- and, again, I need to understand.

So when you ultimately secure a supplier, the supplier of API that you secure wasn't even FDA approved to provide the API at the time that you launched. You end up securing them later because they had to go through whatever approvals and all the rest of it to get it done.

MR. PAK: In essence, that's correct, Your Honor.

If I could just --

THE COURT: Yes.

MR. PAK: With respect to KD Pharma, we were ready to go.

THE COURT: Understood.

MR. PAK: And our ANDA application says we are going to use KD Pharma. KD Pharma says, no, wrong. Can't do it. Amarin came in, took your legs out, basically. So now we have to scramble to go find other suppliers.

When you have four -- and those are the ones that we alleged at least had capacity. But the problem is, one was not FDA approved, and a couple of them -- and all of them, certainly, we did not, quote-unquote, reference in our application.

So the FDA now has to -- FDA says to us, you better go find a supplier that is approved as well as the one that you're going to rely on and then you can begin to get supply and start launching.

That took months. That's why we couldn't supply -- start until June 2021. Your Honor, if they were right that suppliers were readily available in September, why would we have waited? I mean, our whole point was, let's get the drug into the marketplace and compete against Amarin. That's our business model.

If those suppliers were readily available, wouldn't it have made sense for us to do it in October? Why wait? We had to wait, though, because of these regulatory problems, capacity problems, FDA problems. We couldn't start until June of 2021.

THE COURT: Mr. Pak, in your complaint, do you allege that, whether constructively or literally, that Amarin must have been aware of the relationship that you had with KD Pharma? Because you're telling me that at the time that you were in a battle with them regarding their patent, you had identified KD Pharma as your supplier of API even back then during that litigation.

MR. PAK: Yes, Your Honor.

THE COURT: So how can they say now, well, how do we know they had a relationship with KD Pharma? You are saying,

well, of course they knew. They were identified as their supplier when we were trying to get approval for the generic drug in the first place.

MR. PAK: Yes, Your Honor. And we also believe and we did plead this, when they walked into the door of KD Pharma to negotiate a supply agreement, KD Pharma must have said, I'm committed to DRL already.

THE COURT: Because that's what they conveyed to you also, right?

MR. PAK: Since 2013.

THE COURT: We can't move forward with you because we have an exclusive arrangement with Amarin?

MR. PAK: Yes.

THE COURT: Okay.

MR. PAK: Paragraphs 64, 67, 73, 74, 63, various allegations showing that Amarin knew of our relationship with KD Pharma.

THE COURT: Do me a favor, though, because it's helpful for my staff. Read those paragraphs and read them slower. I know they're in your papers, but it's helpful because you may have to pay for a transcript but I don't.

MR. PAK: Paragraphs 62, 64, 73, 74. Well, 63 is about BASF.

THE COURT: And these are paragraphs where you're saying, look, we've identified in their allegations that

Amarin was aware of our relationship with KD Pharma and interfered with it. Those are paragraphs we should be focused on.

MR. PAK: Again, that's -- that's for the tortious interference portion.

THE COURT: No, no. I got you.

MR. PAK: Just to get to the point of launch versus what's the injury here, remember, that's why it was only starting in June of 2021 that we were able to start selling. And even then, and through the end of 2020 -- and I realize this is outside the scope of the complaint -- we're not getting enough supply of API because of the pre-existing exclusive contracts that Amarin has as well as capacity --

THE COURT: When you said that's outside the scope of the complaint, are you saying you only pled the delay?

MR. PAK: No, no. We pled the delay and we pled also that our launch, even in June of 2021, was insufficient and not full scale. I'm just telling you of what I know from 10-Qs, 10-Ks, et cetera, from Amarin what has been happening as well as our own sales since June of 2021.

THE COURT: Let me ask you this, Mr. Pak. If you had KD Pharma, and I know there's a little bit of hypothetical here, but I need to fully understand what at least DRL's position is. If you never lost KD Pharma and you moved forward with them, even if Amarin had secured the other four

suppliers of API, would you have an argument here that there was some problem, or you would have moved forward with your drug, you got your supplier, it doesn't matter that they secured four other suppliers because there was at least one out there that you could work with?

MR. PAK: I haven't tested that literally, Your Honor, but I do believe it is true because DRL is a sophisticated generic drug manufacturer. They've done this many, many times with many suppliers and other drugs. They lined up KD Pharma in 2013 and said, they look good. They have capacity. They're going to get FDA approval, et cetera. We are going to reference them in our ANDA application.

There's a reasonable inference I think from there that KD Pharma would have been sufficient for our needs. And if we did have KD Pharma with us in September of 2020, we would have launched right then and there.

THE COURT: It's your position that Amarin didn't need KD Pharma; they had sufficient supply of API. The sole purpose of why they also secured KD Pharma as another supplier was to prevent competition when you guys were going to launch your generic because you wouldn't be able to really do much with it without the active ingredient?

MR. PAK: That is very true, Your Honor. And remember, another component to this, it's antitrust law as well, but it's also factual. Throughout this time and leading

up to 2020, remember, Amarin is a one-drug company, Vascepa®, the branded version. That's the only product it has.

And it's telling its investors in conference calls and 10-Ks, we're the monopolist. We control supply. Now, we know generic competition is going to happen some day. But if we keep API suppliers out of the hands of generic drug companies, we are going to be able to delay that entry.

And every month or day in which Amarin is able to hold on to its monopoly position means it earns monopoly profits.

So even those ten months, Your Honor, in which we were delayed from September 2020 to June 2021, that's ten months longer that Amarin earns monopoly profits.

THE COURT: Now, let me ask it because, again, I don't have it memorized.

Is that alleged in the pleading?

MR. PAK: It is, Your Honor.

THE COURT: All right.

MR. PAK: Of course, then we talked about the law -- I'm sorry, they talked about the law. And as you pointed out, I don't think there's a motion to dismiss case granted, particularly in a pharma case, along the allegations that we've alleged here that says, you're right. That delayed generic entry, you could have done better. It's your own fault. There's been no harm, et cetera. Exclusive supply contracts are great. No discovery needed. Nothing.

Just to the contrary. Third Circuit, Second Circuit, numerous cases talk about the problems of generic -- I'm sorry, of delayed entry and the harm that exclusive contracts can create.

And it is important to remember this, Your Honor, because drugs are different from other products in this way. It's -- these aren't fungible in this regard. You need the API. Without it, you can't make the drug. It's not like upstream competition elsewhere where you can go look for another supplier. There are only a limited number of API suppliers that are available to you at that time.

They may become available to you later, but that means during that interim period, no generic competition. That's why courts really care about this area and say, Third Circuit, Second Circuit, many other circuits, generic drug delayed entry competition, et cetera, anything that the monopolist does to delay that entry can have anticompetitive harm.

They said there's no antitrust injuries here. I find that hard to believe how they could say that. We brought prices down. That's what generic drugs do. So, of course, during the time when we're not allowed to enter, there's harm because but for their anticompetitive conduct, consumers would have had cheaper drugs and cheaper prices.

Also, Your Honor, with respect to this field, pharma exclusive dealing arrangements, et cetera, there's particular

care paid attention because of that harm. There's very little doubt within courts that these kinds of things can cause anticompetitive harm and effects.

And that's ultimately what we're looking for in terms of antitrust law: the harm to competition, the harm to consumers. It's a given that delayed generic entry causes anticompetitive effects.

Now, in other areas outside generic drugs, you will do much more of a balancing test because it's not so clear whether the competitor that has been foreclosed had other means of getting their product to the marketplace, thereby there wouldn't be harm to competition.

THE COURT: Let me switch gears. I want to go back to KD Pharma because I don't think this has been tacked down; so I want to hear what you have to say about it.

What was the arrangement between DRL and KD Pharma? Was there a contract? Was there an agreement? What was the relationship that you're alleging there was tainted or tarnished or interfered with by Amarin?

MR. PAK: There was a written document, a term sheet. It laid forth what the obligations were going to be. That was done in 2013. Afterwards, we got the FDA approval --

THE COURT: Let's stay there first. So there was a term sheet that had some terms on there between DRL and KD Pharma.

MR. PAK: Yes.

THE COURT: And that talked about what? Supplying API if you get your generic drug on the market?

MR. PAK: Price, quantity, yes.

THE COURT: And was pricing part of that?

MR. PAK: I'd have to look at the contract. I thought it was, Your Honor. And I think it's alleged that it's set forth in there with respect to price and quantity, or at least expectations, goals.

THE COURT: Did you understand that to be an agreement between the parties? That's something that was binding on KD Pharma?

MR. PAK: Certainly, Your Honor, because we went -- we filed the ANDA application. We thought we were going to go to market. When Amarin sued us for patent infringement to keep us out of the market, we fought it because we wanted to come into the marketplace.

THE COURT: What, if any, action did DRL take against KD Pharma when they decided to say, nah, we're good to go, we've got another buddy over here that we're going to work with?

I'm trying to understand the story here. If you tell me that I'm DRL and I've got a relationship with KD Pharma, and then when I finally get my drug ready to launch they go, sorry, we're going to go work with these guys. I'd be pretty

angry about that, and I'd probably take some legal action.

So what I'm trying to figure out is what am I missing in this story?

MR. PAK: That's why I'm hesitating as to whether I can reveal what happened or not because of --

THE COURT: Okay. Fair enough. You may be prohibited from disclosing that answer to my question. Is that what you're telling me?

MR. PAK: Can I ask my colleague, Mr. Sobol?

THE COURT: And by the way, if the answer is, Judge, I want to answer your question, but I don't know if I'm able to because there may be some confidentiality, just let me know that. I'm not trying to put you in hot water. I'm --

MR. PAK: That's why I'm being cautious.

MR. SILBER: Your Honor, Seth Silber from Wilson Sonsini.

As you suggested, it was a significant issue for my client to raise. We did raise it. We did resolve it.

THE COURT: Understood. All right. That's sufficient for me. I just want to get a picture of the story.

It was your position that there was an agreement that they had obligations for and whether that is resolved and how it is resolved is irrelevant.

What your position is, at least for purposes of this litigation, is that Amarin was aware, that they knew of it and

they interfered with that relationship. That's part of your allegation.

At least on the tortious interference side with respect to the antitrust claims, your point about that is, hey, they had four and they took the fifth supplier. And at that point, they were well aware of who was in the market to supply the ingredient at the time you were able to launch. They knew it; they did it for that reason; we were stuck.

And part of our delay was trying to find a supplier that could get through all those approvals and only those five suppliers had at the time of the launch.

MR. PAK: That's right. Without incurring more delay.

And as to the point about the relationship with KD Pharma and where we stood, we were ready, willing, and able to enter the marketplace and launch. We fought the patent infringement suit, we got ANDA approval. We were ready to go. We had a supplier lined up, FDA approved.

We thought they had enough capacity. So we were good to go. And it's because of Amarin's conduct, its exclusive arrangement, that torpedoed us, cut --

THE COURT: How do you allege how Amarin was able to take KD Pharma from you?

MR. PAK: Well, I think, Your Honor, that will be part of the discovery that we would want to see, both from

Amarin -- we definitely want to see from Amarin's perspective. Did they see growth? Or as they said throughout their 10-Ks, they were fearful of the impact of generic competition --

THE COURT: I understand their position. I guess what I was trying to say, in the pleading, do you allege how Amarin was in a position to do that? Are you saying that, look, because they weren't the generic drug, they had been on the marketplace for some time, they were in a position to offer more to KD Pharma than we were as a generic drug to launch?

I mean, how did they get them from you? Or is that even alleged in the pleading?

MR. PAK: Well, I mean, it's alleged in the sense that KD Pharma -- that Amarin was afraid of generic entry. They knew that API suppliers were limited and were the key. And throughout their 10-Ks that's alleged in our complaint, they said we've got things lined up with suppliers so that API supply will be a problem for generic competition. It's in our complaint.

THE COURT: No. No. That's their intent of why they wanted KD Pharma. I understand that.

Do you allege how KD Pharma ended up going to them? What was the incentive for KD Pharma to walk away from you guys to go to Amarin? Or again, is counsel coming up here to say you can't answer that.

And by the way, if that's the case, that's fine. But what I'm trying to figure out is if you're going to allege Amarin interfered, how were they able to interfere? What did they do to get KD Pharma to walk away from DRL?

MR. PAK: There are things like minimum purchase obligations that Amarin would agree to. In other words, we're going to give you money no matter what at a certain price. Those kinds of things are alleged in the complaint. There were financial inducements that Amarin provided to KD Pharma.

THE COURT: Hold up. Counsel's coming.

MR. PAK: Paragraph 73. KD Pharma disclosed to us that they had a binding order for three years from Amarin.

By the way, Your Honor, three years exclusive supply contracts, exclusive dealing agreements, if they're, like, for a year, okay, they're short-term; courts might say that's not harmful to competition. Three years, that's a long time.

That can have a durable, harmful effect on competition.

THE COURT: We're not in The Godfather. You're saying they gave KD Pharma an offer they couldn't refuse.

MR. PAK: They couldn't refuse.

THE COURT: All right. I got it.

MR. PAK: Paragraph 73, 74 and 75 talk about some of the terms.

THE COURT: All right.

MR. PAK: That induced that.

So let me make some other points while I have the stand, Your Honor, about that issue.

As you pointed out, we think we put forth a very plausible claim with factual allegations, as the Supreme Court says, within a heft to sustain this antitrust claim. You pointed out a lot of this in terms of what Amarin is saying is he said-she said.

We state a claim of exclusive arrangements; they admit these are exclusive arrangements that foreclosed competition. Foreclosed not a little bit. 100 percent. Because all the API suppliers that were FDA approved and ready to go at that time were locked up. That's the allegation.

All right. So that's 100 percent foreclosure. That means there's going to be harm to competition.

THE COURT: How was the other company able to launch then?

MR. PAK: That's Hikma. I don't know. They --

THE COURT: I know. Just take a step back.

If you're going to come in here and say all of the API suppliers at the time were locked up, how did that other company launch, if they had no supplier?

MR. PAK: Hikma may have had one of those and had a small amount and therefore they had delayed entry --

THE COURT: But you are saying there's no possibility that there was another supplier other than those five. In any

kind of logic, without knowing what Hikma did, it would have to be they must have been working with one of those five?

MR. PAK: I don't know. Hikma may have had its own exclusive supply contract with somebody else. I just don't know.

THE COURT: But then doesn't that take away from your point that these are the only five suppliers of API if you're saying it's possible Hikma had a sixth?

MR. PAK: But if Hikma had a sixth that was exclusive, that's not available to us anymore then. Right? Amarin had five. And those were the five that were available and had capacity and we think were capable of supplying at some point.

Now, was there a seventh, eighth, ninth, that to me, Your Honor, seems like a question of fact. But as far as we knew, the only ones that had capacity and could reasonably supply at some point, assuming FDA approval, it was five --

THE COURT: I got it.

MR. PAK: Okay. There's a lot of this factual disputes about here's our story. They don't like our story. They want to put in new sets of facts; and therefore -- but that's not permissible on a motion to dismiss.

And if you see the law, Your Honor, lots of cases in this arena are saying, for purposes of a motion to dismiss, this kind of delayed entry, exclusive arrangements, you don't

throw out a case there. You need discovery and you -- at least into summary judgment. And a lot of those cases also say when you're a monopolist --

THE COURT: You know, how -- I see that in the papers, too.

How is this a summary judgment case? If there's all these factual disputes, they're not going to exist at the end of this rainbow. Somehow, by the end of discovery, the parties will all miraculously agree on the facts.

MR. PAK: Actually --

THE COURT: I've never seen a case like that. If you guys want to convince me. I mean, this is one of those cases, either as a matter of law it's going away or it's very likely going to be in the courtroom. No?

MR. PAK: No, Your Honor. I think their documents, their internal documents, will tell us a lot --

THE COURT: All right.

MR. PAK: -- as to what they were thinking, and this is not about intent. It's about their understanding of the marketplace and why they decided to go after these five suppliers and lock them up. We think they knew the impact that would have on competition.

THE COURT: You know, Mr. Cecchi wants to go to trial, and you're now saying that this case may be ripe for summary judgment.

I'll get to you, Mr. Cecchi. You've got a moment.

But you know that he's about to argue against that, right? You're all sitting at the same table.

I mean, he wants a trial next week and you're telling me it may be ripe for summary judgment one day but not at this stage. All right.

MR. PAK: I only have a sense, Your Honor, from prior cases in representing both brand companies and generic companies. And I know the way they think and the way they write and what is -- the dynamics of what's happening.

And what's very clear is that because of the harm that inherently results from keeping generic drug companies out of the marketplace, that's an anticompetitive effect. There is nothing procompetitive out of the marketplace, if you're engaging in certain types of conduct that forecloses those generic drug companies from getting access to key API.

THE COURT: I appreciate that.

MR. PAK: And it is the significance of knowing that anticompetitive harm is likely, Your Honor, that courts tell you do the discovery, let's see what happens. Because -- a lot of antitrust cases, Your Honor, it's really one competitor complaining about another competitor and it's not clear that there's anticompetitive harm.

Generic drug entry delayed is, in fact, anticompetitive harm, because consumers are denied access to those cheaper

drugs. And the monopolist, the branded company, has every incentive to keep generic drug companies out of the marketplace. They will engage in multiple tactics to make that happen. And many courts have said, at a minimum, that's for summary judgment and many have also said that's wrongful conduct.

I think that's it for me, Your Honor, unless you have certain questions.

THE COURT: I appreciate that, Mr. Pak.

MR. PAK: Thank you, Your Honor.

THE COURT: Ms. Bass, you want to come back up, but let me see because I don't know if the DPPs and the IPPs want to add something.

So Mr. Sobol, all right. Here we go.

Let me hear from them, and then obviously I will give you an opportunity.

I will tell you all, though, before I conclude today I am going to want to recess for 10 minutes. I want to collect my thoughts just to make sure that if I have any additional questions, that I strike today while I've got everybody here.

So I will likely recess for ten minutes or so, collect my thoughts with my notes with my staff, make sure I don't have anything outstanding that I want to raise with either of the parties. And that way I get a full experience from your argument as well as you guys.

So just to give you a heads-up, we'll take a break probably soon, but I don't want to cut off Mr. Sobol.

MR. SOBOL: Thank you, Your Honor. Mr. Sobol for the indirect purchasers.

I'm going to try to make this fairly quick, but I first want to see what I can do to give a little bit of generic entry 101, if I may. A paragraph or maybe a paragraph and a half.

And the reason I do that is because the issue before you in large part is what's substantial foreclosure of the market? Right. Well, obviously, substantial foreclosure of a market might be different for automobiles that are new or old; it might be tuna on the dock in Gloucester. And it's certainly different for pharmaceuticals.

And since you have acknowledged in other situations that you may not be as familiar with this, let me just give this very brief background.

THE COURT: Sure.

MR. SOBOL: Okay. So there's -- the reason you see so many of these drug cases is that there's a phenomenon called "monopoly to commodity" overnight here.

So the way that the statutory and the regulatory system and the economics work is that there are periods of exclusivities that are given to brand companies. Exclusivities might be a patent exclusivity. It might be a

new chemical exclusivity where you developed a new active pharmaceutical ingredient so that you are allowed to be on the market for a period of time there.

It might be pediatric exclusivity. There are all these government-created periods of time during which there's the potential for monopoly power given to the brand company. And then it's supposed to end. That's on the brand side.

What's also interesting here is that the generics have a product which by law is the same as the brand drug. Literally the same as. And, therefore, because you've got these two dynamics and you've got overlay on that, other things, like automatic substitution by the state laws, that kind of thing. When a drug goes generic, even if it's only one generic, that drug goes from monopoly to commodity in months, 80 percent. And we plead that. We plead all this boring stuff at the beginning of the regulatory section of our complaint, but it's important to understand.

And so not only do you see, then, when even just one generic comes on the market that there's this huge movement over from the branded company to the -- to the generic within -- you know, many drugs, even within a month, right.

Then you also see prices. So the brand price is up here. When the first generic comes on, if they're the only generic come on, well, they'll dip it down somewhat, but they're going to milk it for a period of time. Once you get

multiple generics, the price is down here. And that's just what happens.

So now that's the first thing I wanted to identify.

The second thing regulatory-wise is that in order for the generic to enter the market, the generic has to have an active pharmaceutical ingredient supplier that has an approved drug master file, an approved DMF, and that that DMF is attached to their ANDA. Pretty straightforward.

Now, what do we allege, therefore, happened here by way of foreclosure, just so that we can make sure it is clear that there is, in our view, from our allegation, substantial foreclosure.

As to Hikma, paragraphs 139 through 144 of our complaint, they were delayed from May 2020 to November 2020 completely. And then, even by July of 2021, so that's another eight months or thereabouts, but it's a full year after there has been generic -- there should have been generic entry. Hikma only had nine percent of the market by way of unit sales rather than 80 percent. So the delta there is 71 percent. That sounds like substantial foreclosure to me.

As to DRL, paragraphs 145 through 150, we allege that DRL should have and would have gotten onto the market in August of 2021, when it got its final FDA approval, but instead was completely blocked until June of 2021. And we also allege that even as late as August of 2021, with both of

those generics now on the market, there's only 12 percent penetration when there should have been 80 percent. And that's why we say that there was substantial foreclosure.

Now, if I were a busy Article III judge, and I hope never to be one, I would --

THE COURT: I don't know where this is going; so I'll caution you now, but I'm going to let you finish that sentence.

MR. SOBOL: I would try to find the one-stop shopping where the law is laid out that would help --

THE COURT: I thought you were going to say dismiss the case, and that's one case off the docket. You should go sit next to Mr. Baton and Ms. Bass over there.

MR. SOBOL: I would say mark the case up for trial because you'd want to see Mr. Hester as defense lawyer handling things. He's quite good.

So I would go to the *Fresenius* case that's been cited by the parties, 841 Federal Appendix 399 at Footnote 12, and Footnote 12 provides you all the case law you need because it cites all the prior Third Circuit cases. And this is a footnote in the Third Circuit case and it tells you what substantial foreclosure is. It tells you what we have to prove: three things, substantial foreclosure number one, which I'll trim back to in a second. Second, likely or actual anticompetitive effects. Well, that we have absolutely writ

large, because as Mr. Pak pointed out, if you delay generics even a day, you have your delay substantial -- that's a substantial price effect. And third, if the conduct is by a monopolist, that's uncontested here.

So then going back to what this footnote tells us, what we look at, what are the things that we look at for this particular decision? One is look at industry practices. Well, we plead in our complaint that a brand company lines up two suppliers and that exporting, if it alines up, five.

Second, you look at whether generics have bona fide opportunities to be able to enter the market. Here we plead that the known DMFs that were approved at the time of the final approvals for each of these two generic companies have been hoarded by the defendant Amarin because of the approved DMFs.

We also plead that it takes time to be able to either have somebody else get an approved DMF, and/or even if they have an approved DMF, get that DMF attached to your ANDA.

That footnote also says that there are lots of wildly factual disputes in these things, particularly about the viability of other sources. That's the word it uses. It then cites the *Geneva* Second Circuit case, which was a case much like this one, showing where the Second Circuit reversed a grant of summary judgment for a defendant because there were factual issues. The Third Circuit points to that case and

said in that case, I'll point out, had a period of delay that was only one year. Here we have pled that the lasting effects because this market is completely depressed.

To conclude, this is housekeeping.

THE COURT: Okay.

MR. SOBOL: The remarks -- there have been several remarks that were under seal that have been before you. They're all the good, interesting stuff, like, you know, what happened with the supplier right on the eve of DRL, particularly DRL's paragraphs 73, 74, the discussions regarding the buying up the metric tons, i.e., buying up 90 percent of the market from one manufacturer, even though you already have four other DMFs lined up. So there will have to be some cleaning up of the record, Your Honor. These are my remarks.

THE COURT: I think for now we agree that the transcript of today's proceedings will be sealed. Counsel can review and confer and circle back. I appreciate your comments, Mr. Sobol.

MR. ROBERTS: Your Honor, Hi. I'm Michael Roberts. I represent KDH and the Direct Purchaser. Thank you.

THE COURT: Good to see you.

MR. ROBERTS: Nice to be here.

THE COURT: Do you like this strategy I have? That in the middle of lunch I'm pushing you guys through without

eating or taking a break. I will last longer than you, I promise. I don't even eat. We're machines over here. I see some eyes fading. It doesn't bother me at all. We're going to push right through this argument. Then we're going to recess. I'm going to see you back in ten minutes if I have questions. Then I'm going to let you all go home.

Go ahead, Mr. Roberts.

MR. ROBERTS: Your Honor, I have about 45 minutes and I'd like to reserve 15 on the end.

THE COURT: Woah.

MR. ROBERTS: Just kidding. About five minutes, Your Honor.

THE COURT: Of course. I'm happy to hear from you. I don't want to cut you off. I do know there's a lot of overlapping issues. To the extent you want to highlight anything in particular for your particular plaintiffs, let me know. I know there's a lot of overlap.

MR. ROBERTS: Your Honor, I will not touch any of the issues that have already been discussed other than to say that I agree with my colleagues.

There is one issue that is unique to KPH and that is that of standing. The defendants raise that in their motion to dismiss, and briefly I'd like to address it.

Your Honor, there's no dispute that KPH has standing, Article III standing, to bring this lawsuit. Even the

defendants don't dispute that. What they are trying to do is conflate the language of the assignment, the assignment which is attached to Mr. Baton's declaration. That assignment is between KPH and McKesson. McKesson is the assignor, KPH is the assignee.

If you look very closely at that language, which they -- which they emphasize in their brief, you see very clearly that the language does not indicate or say what they want it to say. Paragraph one of page two of that assignment, Your Honor, states -- and I'm just going to read it to you, if that's okay, Your Honor.

THE COURT: I'm happy for you to do it, and that will be helpful for me and my folks.

MR. ROBERTS: Here it goes: McKesson hereby conveys, assigns, and transfers to customer 100 percent of all rights, title, and interest, and to any antitrust cause of action it may have against manufacturers, suppliers, and under the laws of the United States or any state: A, so long as the cause of action is the manufacturer's -- is that the manufacturer unlawfully delayed or frustrated the introduction or sale of generic Vascepa®. And, B -- this is the operative language -- only to the extent that the cause of action arises from McKesson's purchases of Vascepa® that were subsequently resold to customer during the period from November 1st, 2013, through the date of this assignment.

Subparagraph B of that paragraph 1, Your Honor, highlights -- or limits the assignment only to the extent that the cause of action arose during the time period that the two parties were doing business. At no place in this assignment, especially this paragraph, do the parties limit the relief that could be brought. For example, here's a hypothetical. You take a personal injury plaintiff who's involved in a car wreck, has brain injury. Of course the cause of injury occurred on that date, but the relief is not limited. It's the exact same in this particular instance, Your Honor.

And that's the plain language of the assignment, Your Honor. They're trying to conflate the language. If it had said -- if it had said only to the extent that the relief arose during that time period from November 13 through the date of this assignment, which was in June of '21, that would be a whole different story. But it didn't say that. They're trying to rewrite the assignment.

So, Your Honor, that's my point on the assignment. Of course, we have Article III standing. Of course, the case law that we've cited in our brief allows for amendments, even if you were to adopt their argument. But I don't think you even have to get there, Your Honor. The assignment is clear. That's all I have.

THE COURT: Thank you, Mr. Roberts. I appreciate your time.

MR. ROBERTS: Thank you.

THE COURT: Anyone else from plaintiffs' side of things, or anything we're missing? We're okay?

MR. CECCHI: We're done.

Judge, in the spirit of Mr. Sobol's one-stop shopping on the state law issues, which were very briefly mentioned by Amarin, I would just refer Your Honor to Judge Linares' decision in *Liquid Aluminum Sulfate*. I would ask Your Honor not to tell Judge Linares that I referred to one of his cases. Thank you.

THE COURT: All right. I presume that's in the brief, too?

MR. CECCHI: It is.

THE COURT: I appreciate you identifying it on the record.

Ms. Bass? I apologize. I may have called you Ms. Barns earlier. I want to apologize for that. I can't read my own handwriting sometimes. You guys want a little bit of rebuttal on some of these points, and I will hear from you so you can complete your record.

MS. BASS: Thank you. So, Your Honor, there's four points that I would like to address on rebuttal. So to begin with, in the DRL presentation and also in the IPPs presentation, there was a good bit of discussion about this conception of monopoly to commodity overnight and Amarin being

a monopolist and the benefits of generic drug competition in the United States. But there's a couple of facts, as pled in the complaint, that demonstrate that this case is not like most cases.

And the first is that the generics here only have approval for Amarin's first indication. That is a small fraction of the marketplace. The generics DRL and Hikma didn't have approval for the second indication. They carved it out of their label. So this concept that once the generics entered they should have taken some vast amount of the marketplace, I think 80 percent was the number that was suggested, simply on the basis of studies that had been published before and other experiences that do not translate here based off of the actual facts as alleged in the complaint.

As I mentioned before when I was up here, in the DPP complaint, at paragraph 87, at footnote 84, there's an article where the amount of the first indication is estimated to be seven percent of the Vascepa® sales.

So, again, I think based off the complaint, the facts as pleaded in the complaint and this press article that was cited in their own complaint, it's very important to contextualize that this case is not like a normal generic competition case.

We also take issue with the concept that the generics

have somehow driven price competition here. They didn't plead anything about their own pricing, the generics pricing in the complaint. Certainly there's no comparison of net-to-net pricing or anything of that nature. And the cases where they have pointed you to where they claim that there were issues with supply agreements are ones where there was extreme price increases that were taken. In the *Fera* case the price was increased by a thousand percent. In the *Fresenius Kabi* case the price was increased by 26,000 percent.

So the concept here that there's monopoly pricing, or something of that nature, is not supported by the factual allegations. So that's one thing, Your Honor. There were various times where various things were said in the arguments before you, but when you check the facts in the complaint they're not there to support that notion. Indeed, there's no allegation that DRL brought the price down because when DRL filed their complaint they hadn't even yet launched.

So the second point that I wanted to discuss was the concept that there are differing kinds of launches. That's where we started out with the DRL discussion. And maybe launches can be limited and maybe they won't be kind of the full launch that a generic competitor might desire. One thing that wasn't touched on in that argument is BASF. BASF is one of the competitors that they claim that we locked up. Yet with BASF, DRL's own complaint, at paragraph 114, said that

BASF has sufficient capacity to support a timely launch without having first to expand capacity.

So, again, the concept that there's some sort of a limitation on the launchability here is belied by their own allegations that are in the complaint. BASF is a supplier that agreed to supply DRL in September of 2020, and their own allegations say that there was no limitation on the amount that BASF could provide in a launch. So there's no allegation of some sort of a limited supply issue with BASF.

The third issue is the KD Pharma knowledge issue. I wanted to go back to that. What's actually pled in the complaint is that the information was known to Amarin that there was a contractual relationship between KD Pharma and Amarin because of documents that were produced in the patent case. Now, it won't surprise Your Honor that there was a protective order in place in the patent case and that any such references would have been limited in the patent case to only certain individuals and that information could only be used for the purpose of the patent case. DRL makes no well-pled allegations of who at Amarin supposedly violated the protective order and translated that information over to the commercial group so the commercial group could go launch this --

THE COURT: Let me ask you this. Is it Amarin's position that you came to an agreement with KD Pharma and had

no clue that KD Pharma and DRL had a relationship? Is that the position of Amarin?

MS. BASS: There are no well-pled facts.

THE COURT: I'm asking. Your position is that, or your position is they didn't plead that?

MS. BASS: It's both, Your Honor. So the allegation here is that there was some sort of a breach of information in the patent case and that that information then was used to then disrupt the relationship with KD Pharma and with DRL. That's not plausible and it didn't happen.

THE COURT: They alleged that you were aware of the relationship. I guess let me ask it a different way because I think I confused myself. They allege that Amarin was aware of the relationship that they have with KD Pharma before you guys entered into whatever arrangement you did with that company. Is it Amarin's position that that's not true? Although we're at this stage, don't you have to accept that as a true allegation regardless because we're at the pleading stage? Don't you have to say, look, they've alleged that we were aware of the relationship? For purposes of our motion to dismiss, Judge, we don't agree with it but we'll accept it as true for today's purposes.

MS. BASS: The basis of that is the documents were disclosed in the patent action and that the individuals that got the documents violated a protective order and transmitted

that information to someone at Amarin. So --

THE COURT: Mr. Pak, is that your position, that they violated a court protective order and that's how they learned? That seems like a pretty strong allegation to make.

I don't mean to cut you off, Ms. Bass, but I want to tack that down.

In the pleadings, how are you alleging Amarin is aware of the relationship that DRL previously had with KD Pharma?

MR. PAK: Your Honor, two ways. Again, that information being out there during the course of the patent litigation. But also paragraph 74, I was looking at it again. It says: Finally on September 11, 2020, KD Pharma confirmed in a call with DRL that Amarin is the customer that had placed the binding order and had blocked all of KD Pharma's capacity for the API.

THE COURT: So where in paragraph 74 does it say when they did that with KD Pharma they were aware that KD Pharma had a previous relationship with DRL?

MR. PAK: Your Honor, that specific fact is not --

THE COURT: That paragraph says they went to a company they're working with and said, hey, just so we're clear, when you work with us, you don't get to work with anybody else. But that paragraph doesn't say, by the way, we know you had a prior relationship with DRL. They're done.

So what I'm trying to figure out -- and Ms. Bass is

making this point; so I want to tack it down. Are you alleging that Amarin learned of the relationship solely because of the patent litigation, which they would have been in violation of a court order?

MR. PAK: I don't think -- Your Honor, in terms of what's pled, yes, it's part of that. We don't claim any kind of breach of confidentiality. We don't know what happened there. But it seems to me not much of a stretch to infer from the allegation that KD Pharma told us that it was Amarin who had locked them up for the next three years, that KD Pharma did not tell Amarin we have a contract since 2013 to supply DRL. I'm not in the room, Your Honor. Again, seems to me discovery would show whether or not that was true or not.

THE COURT: I don't want my record muddied up. Correct me if I'm wrong: there's no allegation that someone violated a protective order --

MR. PAK: No.

THE COURT: -- in learning of a relationship between DRL and KD Pharma, correct?

MR. PAK: There's no suggestion.

THE COURT: Ms. Bass, the only reason why I interrupted is because I didn't want that in the record if that's not the position they're taking because I don't see why we would have an allegation like that, which would be more problematic than what we're discussing.

I appreciate that, Mr. Pak. I'm going to let Ms. Bass continue. I wanted to tack that down.

So it's my understanding, at least from the representation made by DRL now, they're not alleging any violation of a protective order, but I'll let you continue. I know Mr. Hester has something because he just handed it to you.

MS. BASS: Well, paragraph 171 is the paragraph that says, through discovery and Amarin's patent litigation with DRL, Amarin is aware of DRL's reference of KD Pharma's DMF and its ANDA and its contractual relationship with KD Pharma.

That would have been a breach of the protective order, and that's the basis upon which they claim we tortiously interfered with whatever relationship existed between KD Pharma and DRL. So counsel can say that they're not alleging that there was a breach of a protective order, but that's the allegation upon which they base their tortious interference claim.

THE COURT: So let me ask you this. They have that statement in the pleading. You accept it as true that you've learned of it at least through that. I guess what's your argument?

MS. BASS: The point we made in the papers, that it's not plausible that that's a factual allegation that someone at Amarin breached a protective order, gave the information to

someone in the commercial group --

THE COURT: How is that before me, the protective order and what the breach would be? Is that part of the pleading? Because I don't have any evidence of that. I don't know, based on that paragraph and based on the pleading, that everything you're saying is even part of that narrative.

MS. BASS: You have the fact that counsel just said they have no basis to believe that the protective order was violated. So they made an allegation --

THE COURT: I don't have the protective order. How do I know what it protects? You're saying the protective order specifically protects that KD Pharma was a supplier of API for DRL, correct?

MS. BASS: Yes. The --

THE COURT: We're arguing facts outside of the pleading because I have no idea about that.

MS. BASS: Your Honor, in order for them to make out a tortious interference claim, they need to plead that someone at Amarin, an actual person, had knowledge.

THE COURT: They do. They plead Amarin was aware of the relationship and we plead that they interfered with it. And we also spoke to KD Pharma and they told us Amarin said this to them.

MS. BASS: They said they entered into a contract with us. There's nothing that says KD Pharma said to say, oh,

we told Amarin that we were working with DRL, and on that basis then Amarin said, okay, we want to enter into a supply agreement for the next X number of years.

THE COURT: They do allege that you guys were aware of the relationship through the discovery of the patent litigation.

MS. BASS: Yes, Your Honor, but there's cases that say that a Court will not take lightly the inference that in order to make out a claim there has been a violation of a protective order, and we cite cases to that effect in our papers.

THE COURT: How do I know that's the position they take if I don't know the scope of the protective order?

MS. BASS: The protective order -- it's an ECF docket number that's referenced in our papers.

Again, there's just -- based off of the allegations that are in the complaint there are no well-pled factual allegations, plausible allegations that Amarin knew of a relationship between KD Pharma and between DRL and -- the whole point of a tortious interference claim is that you have to have that knowledge and then you go and act on it in order to interfere with a contractual relationship. The facts as alleged do not support that and they don't support the broader antitrust allegations as well.

On the last point, on this issue about foreclosure. So

here, again, Hikma was in the market. So, again, this concept that there's generic competition that has been deprived from patients and things of that nature, Hikma was in. Hikma launched. Hikma was selling in the marketplace with the approval for the first indication. So there has been no foreclosure here under the cases that they pointed you to, even the *Fresenius Kabi* case that we went through in some detail in the Third Circuit. The allegation there was that the competitor was completely foreclosed such that they could not file an FDA application. There was never even an FDA application that was filed. They claim that there were supply arrangements that were entered into such that the applicant could not even file an application with the FDA to get approved.

The *Fresenius Kabi* case is one where there was no filing with the FDA, no approval, no launch. Absolute foreclosure. That is not what we have here at all. They want to try to say the delay somehow equals substantial foreclosure, but that's not the case under the facts as they pled them. Hikma launched the day after the federal circuit resolved the issues. There's no allegation that Hikma would've launched any earlier. They launched the second that the federal circuit resolved the issues. And similarly, with respect to the timelines that we've been talking about for DRL, they had full ability to line up, for example, BASF who

was not limited in capacity in any way and signed them up as a provider. Here they did launch within ten months of being able to line up supply. So they lined up two suppliers the month after approval, and they launched in the marketplace within ten months. So the facts of this case are just very, very different than the ones that counsel has pointed you to, like *Geneva*, *Vyera*, *Fera*, and *Fresenius* where there was no entry, or at least entry for an extremely long period of time. For example, in *Geneva* it was a year. No entry for a year. Hikma's there, DRL's there within ten months.

So, Your Honor, I'm happy to answer any other questions, but those are the four points.

THE COURT: I have one for Mr. Pak. He's not off the hook. I'll still give you the last microphone, if you need it.

I need to understand on this tortious interference. Where in the pleading do you allege that the defendant was aware of your prior relationship with KD Pharma, other than they would have learned it through the discovery in the patent litigation? Is that the only place where it's pled that they have knowledge of that prior relationship? Because the other paragraph you identify only has a communication between the defendant and KD Pharma, and I don't think there's an inference in that paragraph that says that they were made aware of your prior relationship. So I need to know, where in

the pleading do you have that?

MR. PAK: Your Honor, I think it's a reasonable inference --

THE COURT: I don't necessarily agree. I'm not going to make that finding today, but I have concerns about it.

MR. PAK: I understand, Your Honor. We talked about this other action against KD Pharma, and I think discovery will show that, in fact --

THE COURT: You have to plead it first. You only get to discovery if you sufficiently pled the claim. You have to at least make a claim that they were aware of the prior relationship. How could they interfere with your arrangement with KD Pharma if you haven't pled they knew about it? You guys pled, hey, we spoke to KD Pharma, and they told us why don't you ask them? You must have conveyed to the defendant that we had a prior relationship, right? Yes. Then you could have pled it. If you had the first information, why not swing at the second?

MR. PAK: Your Honor, the law on tortious interference in New Jersey says it's not literally direct knowledge. It could be constructive knowledge.

THE COURT: Your constructive knowledge is based on a patent litigation where I'm going to go look at a protective order, and you're telling me on the record that you're not alleging any violation of the protective order. So if we

remove that, where in the pleading do you have them having knowledge of the prior relationship? If it's the patent litigation and there's a protective order and the protective order would've covered that relationship, and you on the record are telling me we're not alleging a violation of that order, then you have zero pleading. You have zero allegation in the pleading where it says they knew about the relationship. So that's why I'm trying to figure out from you all, is there anything more?

MR. PAK: If you would permit, I'm going to go back to --

THE COURT: Did you understand? Are you following my logic?

MR. PAK: 100 percent.

THE COURT: You guys are saying it's coming from the litigation. We're not saying they violated anything. And now Ms. Bass is telling me that has to be the allegation because that's the only thing they're alleging we knew of them. How do you get around that?

MR. PAK: I'm going to go back and --

THE COURT: Okay.

MR. PAK: If it's there, it's there. If it's not there, it's not there. But there's a point that I want to make about this. That's the tortious interference claim.

THE COURT: I know. By the way, I said, I only want

to talk about tortious interference. I don't want to go back. We're not going back in time, everybody. I'm very specific on this. Although, I'll give Ms. Bass the last word if you come back with something out of that complaint. Somebody should be looking at that pleading and telling me where in there is your tortious interference claim going to survive? Because that's a glitch.

Now, I will tell you, if you don't have it, there's going to be a problem. So let me know.

MR. PAK: Understood, Your Honor.

THE COURT: Ms. Bass, you don't have anything more based on what I'm asking plaintiffs' counsel to do, correct?

MS. BASS: No, Your Honor.

THE COURT: All right.

MR. SOBOL: We're all set.

THE COURT: What do you mean we're all set? Are you guys coming back with something?

MR. SOBOL: No. We're waiting for you to stand up and say, "I'll be back in ten minutes."

THE COURT: So there's nothing more?

MR. PAK: We were waiting for the ten minutes, Your Honor.

THE COURT: You want to do it on my break?

MR. PAK: Yes.

THE COURT: I was going to make you do it right this

second. Fair enough.

MR. CECCHI: I'm ready for the opening, just so you know.

THE COURT: I don't want to go back in time. We don't need to talk about antitrust claims, but I do want to hear from you on tortious interference. I only know that's one part of it. That one we need to tack down before you leave today.

Why don't we all do this? Take a break, whether restroom or otherwise. Do you want longer than ten minutes?

MR. CECCHI: No.

THE COURT: We're going to do ten minutes. I'll be back on the bench and we'll continue this discussion. Thank you all.

(A short recess occurred.)

THE DEPUTY COURT CLERK: All rise.

THE COURT: You guys may be seated. Thank you.

What do we have from plaintiff's side? Mr. Pak, do you have anything more?

MR. PAK: After the question, Your Honor, on that issue of tortious interference claim knowledge, I'm looking at paragraphs 74 and 56 of our complaint.

THE COURT: 74 and 56. Since there are not that many paragraphs, what does 74 say?

MR. PAK: Let me start with 56, which is Amarin's

investor call statements during 2020. They say, quote, We have heard from various suppliers that they have been approached regarding supplying API for generic use. The suppliers informed us that they turned down such approaches for various reasons, including that they don't have excess capacity.

Your Honor, literally it does not mention DRL.

THE COURT: That's obvious. Okay.

MR. PAK: There's the inference, I think a reasonable suggestion that they were -- Amarin was in communications with suppliers and consistent with our view that they were entering into exclusives.

THE COURT: Before I ask you, let's go to 74 so I know the totality of it.

MR. PAK: 74 is talking about the relationship and the communications they've had between DRL and KD Pharma upon finding out that they weren't going to supply us. KD Pharma tells us that if Amarin cancels the orders over the next 36 months, Amarin would seek very significant damages under the contractual penalty such that KD Pharma had no capacity to supply DRL.

Seems to us, Your Honor, if someone is entering into a minimum purchase requirement covering 36 months, that means there was another supplier -- another entity that was out there that was ready to buy from KD Pharma, and that's why

Amarin --

THE COURT: Even if I agree with you, which I don't necessarily do, this other entity, it has to be you guys. It has to be DRL, not some other person might have been out there. I guess what I'm really confused by, if you had the information you have, and I feel like you have more information than you pled, why don't you just plead KD Pharma told us that they made the defendant aware of our prior relationship and then this is what was told to them? Why am I like trying to pull teeth to find it in the complaint? That's all you've got, 56 and 74?

MR. PAK: Yes, Your Honor.

THE COURT: Look, I'm not making a decision today, but I'm telling you I'm more concerned about your tortious interference claim because I'm not so sure you sufficiently pled it. Ms. Bass makes a strong point about it. I'm not so sure I read that inference there, although it's probably curable, and I'm not going to make a call today. I'm going to have to think about it. I have to tell you, I appreciate you guys identifying the paragraphs. I'm not so sure why you guys couldn't have done more, unless you're telling me that's all we know, but it seems like you're privy to information from KD Pharma and other sources, that you could have just pled KD Pharma advised us that they made the defendant aware of our prior relationship. Then they told them three-year

relationship, no "this," exclusivity, you can't go to anybody else. It just seems like it would have been easy for you guys to do that.

I'm going to consider what you have. I'll consider paragraphs 56 and 74. I'm not making a decision today on the bench, but I will tell you I've got serious concerns. That being said, if I end up going that way and agreeing with the defense on your tortious interference claim, you'll have an opportunity to amend on that. I'm letting you know that's where I am.

Ms. Bass, anything further, though only on tortious interference and only on the issue I let Mr. Pak address since I want you to have the last word?

MS. BASS: No, Your Honor.

THE COURT: Anything else from any of the plaintiffs' counsel?

MR. CECCHI: No, Your Honor.

THE COURT: I will just briefly say it's days like today that I think we should have more oral argument. One, I just want to thank the counsel for what I thought was excellent advocacy on behalf of all your clients. This is another reason why I have my term law clerk here. I think it's fantastic when you get to have younger attorneys have the opportunity to see experienced lawyers really argue their motions or their cases.

I will hold to what I said earlier off the record, which this does not mean you should request oral argument in every case. That being said, you really give me some pause on maybe having an opportunity to do this a bit more. It also clarifies some of the issues for me, and I think it's beneficial to counsel and your clients to have an opportunity to see what the Court is concerned with and what questions I have.

I want to thank defense counsel and all the plaintiffs' counsel that spoke. I know there's a lot of attorneys here also appearing. I do appreciate your time. I know I kept you here a little bit longer than you anticipated, but I think it was worth it. Your motion is on my radar. I will get to it sooner rather than later. Thank you all. This matter adjourned.

THE DEPUTY COURT CLERK: All rise.

(Court concludes at 1:19 p.m.)

FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

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**/S/ Megan McKay-Soule, RMR, CRR** **September 28, 2022**

Court Reporter Date

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